#### FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

#### Arthritis Advisory Committee (AAC) Meeting

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503) 10903 New Hampshire Avenue, Silver Spring, Maryland July 13, 2016

#### DRAFT MEETING ROSTER

#### **ACTING DESIGNATED FEDERAL OFFICER (Non-Voting)**

#### Moon Hee V. Choi, PharmD

Division of Advisory Committee and Consultant Management Office of Executive Programs, CDER, FDA

#### **ARTHRITIS ADVISORY COMMITTEE MEMBERS (Voting)**

#### Mara L. Becker, MD, MSCE

Associate Professor of Pediatrics University of Missouri-Kansas City Director, Division of Pediatric Rheumatology Children's Mercy Kansas City Kansas City, Missouri

#### Beth L. Jonas, MD

Director, Rheumatology Fellowship Training Program University of North Carolina School of Medicine Chapel Hill, North Carolina

#### Andreas M. Reimold, MD

Chief of Rheumatology
Dallas VA Medical Center
Rheumatology Section, Medical Service
Dallas, Texas

#### **TEMPORARY MEMBERS (Voting)**

# Diane Aronson, BS in Ed.

(Patient Representative) Naples, Florida

#### Jennifer Horonjeff, PhD

(Consumer Representative)
Research Fellow & Patient Advocate
Center for Immune Disease with Onset in Childhood
Division of Rheumatology
Department of Medicine Columbia University
Medical Center
New York, New York

#### Donald R. Miller, PharmD, FASHP

Professor of Pharmacy Practice School of Pharmacy North Dakota State University College of Health Professions Fargo, North Dakota

#### Wilma F. Bergfeld, MD, FAAD

Professor of Dermatology and Pathology Senior Dermatologist & Emeritus Director Dermatopathology Director, Dermatopathology Fellowship Departments of Dermatology and Pathology Cleveland Clinic Cleveland, Ohio

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# Arthritis Advisory Committee (AAC) Meeting July 13, 2016

## **DRAFT MEETING ROSTER (cont.)**

#### TEMPORARY MEMBERS (Voting) (cont.)

## Warren B. Bilker, PhD

Professor of Biostatistics Department of Biostatistics and Epidemiology Perelman School of Medicine University of Pennsylvania Philadelphia, Pennsylvania

## William Hancock, PhD, DSc

Professor
Department of Chemistry and Chemical Biology and
Barnett Institute
Bradstreet Chair of Bioanalytical Chemistry
Northeastern University
Boston, Massachusetts

#### David J. Margolis, MD, PhD

Professor of Dermatology Professor of Epidemiology University of Pennsylvania School of Medicine Philadelphia, Pennsylvania

#### June K. Robinson, MD

Research Professor of Dermatology Northwestern University Feinburg School of Medicine Chicago, Illinois

#### Joseph Shiloach, PhD

Head
Biotechnology Core
National Institute of Diabetes and Digestive and
Kidney Diseases, NIH
Bethesda, Maryland

#### Erica Brittain, PhD

Deputy Branch Chief and Mathematical Statistician Biostatistics Research Branch National Institute of Allergy and Infectious Diseases (NIAD) National Institutes of Health (NIH) Bethesda, Maryland

## Donald E. Mager, PharmD, PhD

Professor of Pharmaceutical Sciences University at Buffalo, SUNY Buffalo, New York

#### Alyce M. Oliver, PhD, MD

Professor of Medicine Director, Rheumatology Fellowship Training Program Ambulatory Medical Director of Medicine Medical College of Georgia Augusta, Georgia

#### Jose U. Scher, MD

Assistant Professor of Medicine
New York University School of Medicine
Director, NYU Psoriatic Arthritis Center
Director, NYU-Langone Hospital for Joint
Diseases Arthritis Clinic
Director, Microbiome Center for Rheumatology
and Autoimmunity
New York, New York

#### Richard Siegel, MD, PhD

Senior Investigator and Chief Autoimmunity Branch Clinical Director National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH Bethesda, Maryland

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# Arthritis Advisory Committee (AAC) Meeting July 13, 2016

## **DRAFT MEETING ROSTER (cont.)**

#### TEMPORARY MEMBERS (Voting) (cont.)

#### David Solomon, MD, MPH

(Acting Chairperson)
Professor of Medicine
Harvard Medical School
Chief, Section of Clinical Sciences
Division of Rheumatology
Division of Pharmacoepidemiology
Brigham and Women's Hospital
Boston, Massachusetts

## Yihong Ye, MD, PhD

Senior Investigator National Institute of Diabetes, Digestive, and Kidney Diseases, NIH Bethesda, Maryland

## Scott A. Waldman, MD, PhD, FCP, FAHA

Director, Gastrointestinal Cancer Program of the Sidney Kimmel Cancer Center Samuel M.V. Hamilton Professor of Medicine and Chair, Department of Pharmacology and Experimental Therapeutics Sidney Kimmel Medical College Thomas Jefferson University Philadelphia, Pennsylvania

#### ACTING INDUSTRY REPRESENTATIVE TO THE COMMITTEE (Non-Voting)

#### Sean P. Curtis, MD

Head, Global Scientific Affairs Merck Research Laboratories Merck and Co, Inc.

#### FDA PARTICIPANTS (Non-Voting)

#### Leah Christl, PhD

Associate Director Therapeutic Biologics Therapeutic Biologics and Biosimilars Staff Office of New Drugs (OND) CDER, FDA

# Nikolay P. Nikolov, MD

Clinical Team Leader DPARP, ODE-II, OND, CDER, FDA

## Badrul Chowdhury, MD, PhD

Director
Division of Pulmonary, Allergy, and Rheumatology
Products (DPARP)
Office of Drug Evaluation II (ODE-II)
OND, CDER, FDA

## Steven Kozlowski, MD

Director Office of Biotechnology Products (OBP) Office of Pharmaceutical Quality (OPQ) CDER, FDA

## Peter L. Adams, PhD

CMC Product Quality Reviewer
Division of Biotechnology Research and Review I
OBP, OPQ, CDER, FDA